

### DETAILED ACTION

This action replaces the non-final action that was mailed 04/06/09. The previous action inadvertently included a graphic that blocked out some of the text.

#### *Information Disclosure Statement*

1. The information disclosure statement filed 02/02/09 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. References that have not been considered are noted on the IDS 1449.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

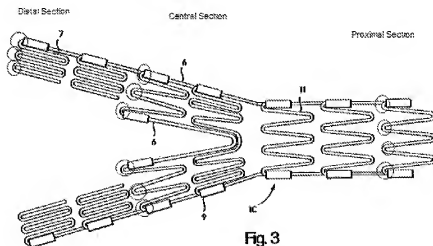
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-10, 15, 38, 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy et al (US 6,086,611) in view of Jervis (US 5,067,957).**

4. Duffy discloses a self-expanding stent (Fig. 3) for treating a bifurcated vessel. The stent has a plurality of rings (7 and 11) aligned along a common axis, adjacent rings being connected by links (6). The stent has a proximal section, distal section and central section (see below) each such section being defined by selected rings of said plurality of rings. The number of first peaks (indicated by circles in figure below) in each

Art Unit: 3731

of the rings of the central section differs from the number of first peaks in the rings of the distal and proximal sections thereby providing additional material for apposing a side branch vessel. The first peaks of the rings of the central section are configured to (capable of) flare outward radially into an opening to the side branch vessel (see Figs. 6A-6C). The proximal section has 7 first peaks. (The proximal section shows 4 peaks. It is inherent that there are at least three on the side not shown.) The distal section has 6 first peaks. (The distal section shows 3 peaks. It is inherent that there are at least three on the side not shown.) The central section has 8 peaks. (The central section shows 6 peaks. It is inherent that there are at least two on the side not shown.) The number of first peaks in the rings of the central section is greater than the number of first peaks in any of the rings of the proximal or distal sections. The distal opening and the proximal opening are aligned along the stent longitudinal axis (depending on what type of bifurcated vessel the stent is delivered to & when the stent is the delivery configuration (fig. 4)). The central opening is offset radially from the proximal and distal openings.



5. Duffy does not disclose that the stent is self-expanding, but rather discloses a stent made of shape memory material requiring a heat induced transformation (C7: L16-24). However, Jervis disclose the use of medical devices made from stress induced martensite (SIM) alloy. He discloses that SIM can be substituted for conventional shape memory alloys (SMA) to achieve beneficial effects (Col 3, lines 15-20). Devices using SIM are able to use the advantageous properties of SMA without the difficulty of alloying control and/or temperature control of placement or removal needed by SMA (Col 2, lines 23- 58).

6. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate stress induced martensite (self expansion) into the stent of Duffy since it would be an improvement over the temperature reactive stent by preventing trauma to the tissue caused by an extreme change in temperature. Duffy substantially discloses the claimed invention except for a heat induced shape memory alloy instead of self-expansion. Jervis shows that self-expansion (stress induced martensite) and heat-induced expansion are equivalent structures known in the art. Therefore, because the two types of shape transformations were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute one for the other, since substitution of one known element for another would have yielded predictable results namely a way of expanding a stent made of shape memory alloy.

7. As to claim 42, Duffy teaches a bifurcated stent substantially as claimed but does not disclose that the stent is formed from a single hypotube. The claimed phrase

"formed from a single hypotube" is being treated as a Product by Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

8. Thus, even though, Duffy forms the stent by a different process, it appears that the product disclosed by Duffy would be the same or similar as that claimed; especially since both applicant's product and the prior art product are a bifurcated stent with a middle section that flares into the branch vessel.

**9. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy et al (US 6,086,611) in view of Jervis (US 5,067,957) as applied to claim 1 and further in view of Guruwaiya (US 6,251,136).**

10. Duffy modified by Jervis discloses the invention substantially as claimed except for the layer of drug and the primer material. Guruwaiya discloses a stent coated with a primer layer, which readily adheres to the material of the stent and is in turn constructed to retain a layer of pharmacological agent (Col 2: L20-34). Guruwaiya discloses that it is well known to be beneficial to deliver drugs with stents to treat problems such as

thrombosis or neointimal hyperplasia. Guruwaiya further discloses using a primer layer of a polymer that more readily carries and releases the drugs as a benefit to layering the drug directly to the stent material.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug layer into the bifurcated stent since it is an old and well known enhancement to be able to treat the tissue with drugs while at the same time providing the treatment of the stent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a primer layer between the stent layer and the drug layer since the primer layer will more readily carry and release the drug that the stent material may not be able to carry and release.

### ***Response to Arguments***

Applicant's arguments filed 01/21/09 have been fully considered but they are not persuasive. Regarding the missing limitation of Duffy's stent being self-expanding, Examiner has addressed the limitations above. Applicant argues that the Duffy reference does not meet the limitation that the plurality of rings is aligned along a common longitudinal axis. Examiner respectfully disagrees. The stent has many axes that extend in the longitudinal direction and thus the stent has many longitudinal axes from which to choose. The claim is not so limiting to require that the axis that is the absolute center of the cylinder be the longitudinal axis. Further the rings merely need to be *aligned along the axis* meaning that rings are aligned and extend along the direction of the axis.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./  
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
4/15/09